IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BURL A. PEVETO	)	CIV. NO.
Plaintiff,	)	**COMPLAINT**
vs.	)	
ETHICON, INC.; JOHNSON & JOHNSON;C.R. BARD INC.; DAVOL, INC.; ATRIUM MEDICAL CORPORATION; MAQUET CARDIOVASCULAR, LLC; MEDTRONIC, INC., COVIDIEN, INC.; COVIDIEN LLC; COVIDIEN PLC; COVIDIEN AG; SOFRADIM PRODUCTIONS and JOHN DOE CORPORATIONS 1-100, inclusive,	)	
Defendants.		

COME NOW Plaintiff BURL A. PEVETO, by and through her attorneys, NAPOLI SHKOLNIK PLLC, and brings the Complaint against Defendants as follows:

INTRODUCTION

1. The action involves the claims of personal injury, economic damages, punitive damages, and other claims of damage arising from the implantation of the Abdominal/Hernia Mesh Medical Devices that were developed, manufactured, supplied, designed, labeled, packaged, distributed, marketed, advertised, licensed and sold by Defendants.

2. At all times relevant herein, Defendants were engaged in the business of placing mesh system medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, advertising, promoting, distributing, labeling, and selling such devices; all hereinafter referred to as "Hernia Mesh."

3. At all times herein mentioned, each of the Defendants acted as the agent, servant, partner, aider and abettor, co-conspirator and joint venture of each of the remaining Defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty.

4. There exists, and at all times herein mentioned there existed, a unity of interest in ownership between certain Defendants and other Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendant, and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as an entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promise injustice.

5. The injuries and damages to Plaintiff were caused by the wrongful acts, omissions, and fraudulent representations of Defendants, many of which occurred within the State of Ohio.

6. At all times herein mentioned Defendants were each authorized to do business within the State of Delaware and did in fact supply the aforementioned products within the State of Massachusetts.

7. At all times herein mentioned, the officers and directors of Defendants authorized and directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct which resulted in the physical injuries described herein.

PARTIES AND JURISDICTION

8. Plaintiff BURL A. PEVETO is a resident of Franklin, Ohio and is now and has been at all relevant times a citizen of Ohio.

9. Defendant ETHICON, INC. is a corporation organized under the laws of the State of New Jersey, with its principal place of business at Route 22 West Somerville, New Jersey 08876.

10. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

11. Defendant ETHICON, INC., and Defendant JOHNSON & JOHNSON are collectively referred to as the "J&J Defendants".

12. On information and belief, Defendant JOHNSON & JOHNSON owns all of the common stock and other ownership interests of Defendants ETHICON, INC.

13. On information and belief, JOHNSON & JOHNSON is either the direct or indirect owner of substantially all the stock or other ownership interests of ETHICON, INC.

14. On information and belief, JOHNSON & JOHNSON, and ETHICON, INC., were the agents, representatives, joint venturers, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other.

15. In doing the acts alleged herein, said J&J Defendants were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service, and employment, with knowledge, acquiescence and ratification of each other.

16. Defendants ETHICON INC, JOHNSON & JOHNSON, are collectively referred to

as the "Defendants".

17. Plaintiff is ignorant of the true names and capacities of Defendants sued herein as JOHN DOE CORORATIONS 1-100 ("John Does") and, therefore, sue these Defendants by such fictitious names. Plaintiff is informed and believes, and upon such information and belief alleges, that each of the Defendants designated as John Does are legally responsible in some manner for the events and happenings hereinafter referred to and caused damages thereby as hereinafter alleged. Plaintiff will seek leave of the court to amend the complaint to show the true names and capacities of the Defendants, and each of them, designated as John Does when the same have been ascertained.

18. On information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America and the State of Ohio.

19. On information and belief, at all relevant times, Defendants have transacted and conducted business in the State of Ohio and/or contracted to supply goods and services within the State of Ohio, and these causes of action have arisen from the same.

20. On information and belief, at all relevant times, Defendants committed tortious acts within the States of New Hampshire, New Jersey, Massachusetts, Rhode Island, and Delaware causing injury within the State of Ohio out of which act(s) these causes of action arise.

I. BACKGROUND AND FACTS

A. Plaintiff's Surgery and the Resultant Adverse Reaction and Failure of the hernia mesh device

21. On or around 11.1.2009 Baptist Medical center and 4.17.2020, Plaintiff was admitted to the McCurtain Memorial Hospital, for hernia repairs. On April 17, 2020 Plaintiff underwent hernia surgery which included a bowel rection due to failed mesh.

22. Had the Prolene hernia mesh device implanted in Plaintiff not failed, he would not have suffered a recurrence of her hernias, adhesions, infection, mesh mitigation and final removal.

23. The hernia mesh device implanted in Plaintiff during his 2009 surgery caused the specific condition, profoundly injuring Plaintiff.

24. As a result of the conduct alleged herein by Defendants, Plaintiff suffered both physical injury, pain and mental anguish, permanent and severe scarring and disfigurement, lost wages and earning capacity, incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendant's defective and inadequate warnings about the risks associated with the product.

25. The hernia mesh device was designed and is manufactured and distributed by the Defendants, who own the patent on the device that was inserted into Plaintiff's body.

26. Defendants designed, manufactured and distributed the Prolene hernia mesh device that was inserted into Plaintiff's body.

27. Defendants, through its agents, servants and employees, participated in the manufacture and delivery of the hernia mesh device that was inserted into Plaintiff's body.

28. Defendants submitted a 510(k) Application to the Federal Drug Administration. Following the 510(k) Application, the hernia mesh device was authorized by the FDA as a Class II medical device.

29. Hernia mesh devices are three-dimensional anatomically shaped pre-formed polypropylene devices and are marketed by Defendants as mesh to be used in repairing hernias and chest wall defects.

30. Defendant's hernia mesh device is made of polypropylene mesh. Despite claims that their material is inert, a substantial body of scientific evidence shows that their mesh material

is biologically incompatible with human tissue and promotes an immune response that is a large subset of the population receiving these products. The immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

31. Defendants' statements made to the FDA regarding these devices inadequately relied on predicate devices and not clinical testing and other design verification testing. These statements induced Plaintiff's implanting surgeon and Plaintiff into relying upon Defendants' judgment.

32. Hernia mesh devices are designed, indicated, and utilized for permanent implantation in the human body.

33. Upon information and belief, Defendants' numerous suppliers, of various forms of polypropylene, cautioned all users in their United Sates Material Safety Data Sheet (hereinafter "MSDS") that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

34. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

35. Hernia mesh devices are constructed of polypropylene.

36. The polypropylene mesh used in the manufacture of the Prolene hernia mesh device, which was implanted into Plaintiff, is not suited for implantation into the human body due to its small pore size and weave, high volume of material utilized, selection of polypropylene resin, and other design features. These design aspects lead to adverse tissue reactions in the body, which directly lead to complications.

37. The Prolene hernia mesh device implanted into Plaintiff was designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair surgeries and was further represented by Defendants to be appropriate, cost effective and suitable product for such purpose.

38. The polypropylene mesh in the manufacture of the Prolene hernia mesh device, which was implanted into Plaintiff, is unreasonably dangerous, defective, and negligently designed in the following ways:

a. The weave of the mesh produces very small interstices which allow bacteria to enter and hide from the host defenses to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages.

b. Polypropylene is impure: there is no such thing as pure polypropylene (hereinafter "PP"). PP contains about 15 additional compounds which are leached from the PP and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis.

c. Mesh is not inert. It flakes and fissures and then leads to degradation and release of toxic compounds. The enhances the inflammatory and fibrotic reactions.

d. With loss of PP due to degradation, the surface area is greatly increased, thus providing greater areas for bacterial adherence and more elution of toxic compounds from the PP, and also the freed toxic PP itself, all of which increases the inflammatory reaction and intensity of fibrosis.

e. By 1998 polypropylene mesh was known to shrink 30-50%.

f. Heat begins the process of degradation.

g. Allergic reactions occur with polypropylene after implantation.

h. Polypropylene is subject to oxidation by acids produced during the inflammatory reaction which caused degradation and loss of compliance.

i. Mesh porosity is important for tissue ingrowth, with low porosity, there is decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress the porosity of the pores is decreased.

j. Pore size should be at least 3mm. The hernia mesh device pore size is much less than; in fact, it has an actual porosity of 1mm.

k. Observation of mesh under the scanning electron microscope reveals that very small interstices exist between the mesh fibrils, which are too small for macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

l. Polypropylene is known to depolymerize, cross link, undergo oxidative degradation by free radicals, and stress crack after implantation in the human body.

m. Polypropylene migrates to lymph nodes when there is a foreign body giant cell reaction.

n. The large surface area promotes wicking of fluids and bacteria and is a “bacterial superhighway” which provides a safe haven for bacteria.

o. Common complications associated with PP include restriction of abdominal wall mobility and local wound disturbances. Often failures of PP include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

p. Kloster Halfen published literature relating to a series of 623 explanted mesh samples removed for pain, infection and recurrence. The examination revealed that the rate of

chronic pain after hernia mesh repair ranges from 4-40%. Thus, defendants should have been aware of these issues with polypropylene.

q. Fibrotic bridging is often observed in mesh variants with pore sizes of 1mm or less which is the typical pore size of heavyweight, small pore PP mesh, like the implanted hernia mesh device.

39. A malfunction of the device can lead to nerve entrapment and damage, fistulae formation, and chronic pain, as well as other chronic and debilitating conditions.

40. Upon information and belief, Defendants failed to comply with the FDA application and reporting requirements.

41. Upon information and belief, Defendants were aware of the high degree of complication and failure rate associated with hernia mesh devices.

42. Upon information and belief, Defendants were aware of the defects in the manufacture and design of hernia mesh devices.

43. Upon information and belief, Defendants were and are aware of the defects in the manufacture and design of the hernia mesh device and chose, and continue to choose, not to issue a recall of these products, including the Prolene hernia mesh device implanted in the Plaintiff, in the face of a high degree of complication and failure rates.

44. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the hernia mesh device.

45. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the hernia mesh device but did not readily disclose ther information.

46. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

47. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

48. Defendants marketed the hernia mesh device to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants' did not undergo pre-market approval for the hernia mesh device and are, therefore, prohibited by the FDA from asserting superiority claims.

49. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the hernia mesh device.

50. Defendants failed to design and establish a safe, effective procedure for removal of the hernia mesh device; therefore, in the event of a failure, injury, or complications it is difficult to safely remove the hernia mesh device.

51. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the hernia mesh device for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

52. The hernia mesh device was utilized and implanted in a manner foreseeable to Defendants.

53. The Prolene hernia mesh device implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

54. Plaintiff repeats, reiterates and realleges each and every allegation of ther Complaint with the same force and effect as if more fully set forth herein.

55. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including the discovery rule and/or fraudulent concealment.

56. The discovery rule should be applied to toll the running of the statute of limitations until he knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that he had been injured and that her injury was caused by the conduct of another.

57. Despite reasonable care and diligence, Plaintiff did not know of facts indicating that he had been injured and that her injuries were caused by the conduct of another until on or about April 2020 when Plaintiff saw advertisements referring to a potential hernia mesh device product liability.

58. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the truth, quality and nature of Plaintiff's injuries and the connection between those injuries and Defendants' tortuous conducts. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her prescribing physicians the true risks associated with their hernia mesh devices.

59. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with use of a surgical mesh during hernia repair surgeries as there was non-public information over which Defendants had and continue to have exclusive control and because Defendants knew that the information was not available to Plaintiff, Plaintiff's medical providers and/or to Plaintiff's healthcare facilities. In addition, Defendants are estopped from relying on any

statute of limitation because of their intentional concealment of these facts.

60. Plaintiffs had no knowledge that Defendants were engaged in the wrongdoing alleged herein and because of the fraudulent acts of concealment of wrongdoing by Defendants; Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

61. Despite the exercise of reasonable diligence, Plaintiff did not discover her injuries until on or about December 2019.

FIRST CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(NEGLIGENCE)

62. Plaintiff repeats, reiterates and realleges each and every allegation of ther Complaint with the same force and effect as if more fully set forth herein.

63. Defendants were regularly engaged in the business of designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing and/or selling medical devices known as hernia mesh devices, for use in abdominal and inguinal surgery to repair hernias or other abdominal wall defects.

64. Defendants owed a duty to design, research, develop, test, manufacture, package, label, market, promote, distribute, sell and/or supply products, including surgical mesh products used for abdominal wall surgery, in such a way as to avoid harm to persons upon whom they were used by adequately warning of the hazards and dangers associated with the use of said products.

65. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were careless, reckless, negligent, grossly negligent and exhibited willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling, and/or placing into the

stream of commerce, surgical mesh products, including hernia mesh devices used for hernia repair, by:

a. failing to design their hernia mesh devices for safe use in hernia repair surgery;

b. failing to conduct adequate and appropriate testing of their surgical mesh products;

c. marketing their hernia mesh devices without first conducting adequate research to determine possible side effects on humans or selectively and misleadingly revealing or analyzing testing and research data;

d. failing to monitor registry data regarding their marketed devices and promptly report any safety concerns that arise through registry study or data;

e. failing to keep abreast of scientific literature and studies which provided Defendants notice of the risks associated with the use of hernia mesh products;

f. failing to appropriately respond to their own and others testing of, and information available regarding hernia mesh devices, which indicated such products' potential harm to humans;

g. failing to appropriately monitor the post-market performance, adverse events, and complications reported about their hernia mesh devices and their products' effects on patients;

h. failing to promptly disseminate new safety information and data regarding their products after their hernia mesh devices reached the market;

i. failing to adequately warn of the actual potential of their hernia mesh devices to be harmful to humans;

j. failing to adequately warn of the actual potential for adhesion and bowel constriction when using hernia mesh devices for hernia repair surgery;

k. concealing their full knowledge and experience regarding the potential that hernia mesh devices were harmful to humans because there was a substantial risk their products would cause bowel constriction;

l. failing to adequately define the patients populations, if any, for which hernia mesh devices could be safely used;

m. promoting, marketing, advertising and/or selling their hernia mesh devices for use for hernia repair surgery given their knowledge and experience of such products' potential harmful effects;

n. failing to timely withdraw products used for hernia repair surgery from the market, restrict their uses and adequately warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

o. failing to fulfill the standard of care required of a reasonably prudent medical device manufacturer;

p. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of hernia repair and its potential harm to humans;

q. failing to provide updated information in the form of reports, statistics and outcomes of studies to physicians, hospitals and other healthcare entities concerning the increased likelihood of bowel constriction when such data became available;

r. promoting the products used for hernia repair on websites aimed at creating user and consumer demand;

s. advertising and promoting their products used for hernia repair as safe and/or safer than other methods of hernia repair; and

t. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of their case.

66. Despite the fact that Defendants knew or should have known that their hernia mesh devices were associated with and/or caused significant bowel constriction, Defendants continued to market, manufacture, distribute, and/or make available their hernia mesh devices to patients through their surgeons and/or health care facilities, including the Plaintiff and her surgeon.

67. Defendants, directly or through their sales staff and/or agents, paid consultants, and/or licensed distributors, among others, made false material representations and/or material omissions through the course of aggressive sales and marketing operations that implemented false and misleading statements by sales representatives, Defendant-sponsored literature, Defendant-sponsored events and conferences, online and/or video marketing, or other promotional material in order to promote and sell their hernia mesh devices while omitting material facts regarding said devices' dangerous side effects and adverse events.

68. Defendants knew or should have known that consumers, such as the Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

69. Defendants' negligence (and/or recklessness) was the cause of and substantial factor in bringing about Plaintiff's injuries, harm and economic loss which he suffered and continued to suffer until her death.

70. Defendants' acted in conscious disregard of, or indifference to, the high degree of risk of physical harm to individuals undergoing surgery with their hernia mesh devices, including Plaintiff herein, of which Defendants knew or has reason to know, giving rise to punitive damages.

71. Defendants knew or should have known of the danger associated with the use of their hernia mesh device as well as the defective nature of said products, but continued to design, manufacture, sell, distribute, market, promote and/or supply their hernia mesh device so as to maximize sales and profits at the expense of the public health and safety.

72. Defendants have done and are doing business in Ohio.

73. Defendants carried on solicitation or service activities in Ohio.

74. The Defendants' hernia mesh products were used within Ohio in the ordinary course of trade.

75. Defendants derived substantial revenue from interstate commerce.

76. As a result of Defendants' negligence and/or recklessness, Plaintiff was caused to suffer serious and dangerous side effects including significant adhesions, hernia recurrence, seroma, physical pain and mental anguish, diminished enjoyment of life, and any and all life complications caused by Plaintiff's injuries.

77. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SECOND CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

78. Plaintiff repeats, reiterates and realleges each and every allegation of the Complaint with the same force and effect as if more fully set forth herein.

79. Defendants' hernia mesh devices were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were designed, produced, manufactured, labeled, sold, distributed, and/or marketed by Defendants.

80. Defendants' hernia mesh devices were defective in design or formulation in that they were not reasonably fit, suitable or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design.

81. Defendants' hernia mesh devices were defective in design or formulation in that they lacked efficacy, posed a greater likelihood of injury and were more dangerous than other available surgical treatment options indicated for the same conditions and uses, including those discussed herein.

82. Defendants' hernia mesh devices were defective in design or formulation in that when they left the hands of the manufacturers and/or suppliers, the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, including those discussed herein, which had more established safety profiles and a considerably lower risks, or by the provision of reasonable instructions or warnings.

83. Defendants' hernia mesh devices, as designed, posed a substantial and avoidable likelihood of harm and it was feasible to design said products in a safer manner.

84. Defendants' hernia mesh devices were defective in design or formulation in that the dangers associated with their use were unknowable and unacceptable to the average or ordinary consumer.

85. Defendants' hernia mesh devices failed to comply with state and federal standards when sold.

86. At the time of Plaintiff's surgery, the hernia mesh device was being used for its advertised and intended purpose, and in the manner Defendants intended.

87. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

88. Due to the aforesaid condition of The Prolene hernia mesh device used on Plaintiff during her surgery, Defendants are strictly liable to Plaintiff.

89. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as ther Court deems proper.

THIRD CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

112. Plaintiffs incorporate by reference the factual portion of the complaint as if fully set forth herein and additionally or in the alternative, if same be necessary, allege as follows:

113. Defendants expected and intended the hernia mesh Products to reach users such as Plaintiff in the condition in which the products were sold.

114. The implantation of the hernia mesh Products in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the products.

115. The hernia mesh Products were defectively manufactured when they were implanted in Plaintiff's body.

116. Defendants knew or should have known that the polyester used in the hernia mesh Products is more likely to cause severe inflammation than polypropylene, despite the coatings that have been applied. Additionally, Defendants knew or should have known that polyester is also less sturdy than polypropylene, creating difficulty during surgery.

117. Defendants knew or should have known that the unsealed edges of the hernia mesh Products would cause the mesh to fray and disintegrate once it was implanted and that once that had happened, organ perforation could result.

118. Defendants' hernia mesh Products are defective in composition, material, physical properties, pore size, mechanical properties, biomechanical properties, elasticity, and engineering.

119. As a direct and proximate result of Defendants' defective manufacturing of the hernia mesh Products, Plaintiff suffered injuries and damages as summarized in ther Complaint.

FOURTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

90. Plaintiff repeats, reiterates and realleges each and every allegation of ther Complaint with the same force and effect as if more fully set forth herein.

91. Defendants were under an ongoing duty to keep abreast of medically known or knowable information related to their products and to advise clinicians of these risks in a timely manner to ensure the safe use of their product.

92. Defendants failed to adequately warn health care professional and the public, including Plaintiff and her surgeon, of the following risks associated with the use of their hernia repair devices, all of which were known or scientifically knowable to Defendants prior to the date on which the Plaintiff underwent surgery in 2016, including, but not limited to:

a. Defendants failed to adequately warn Plaintiff or her surgeons that the coating of their mesh preventing adequate incorporation of the mesh resulting in an intense inflammatory and chronic foreign body response, adverse tissue reaction, migration, and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing;

b. Defendants provided no warning to Plaintiff or her physicians about the risks or increased risks specifically associated with design of their mesh. The Defendants' Instructions for Use provided with their mesh expressly understates and misstates the risk known to be associated with their mesh products.

c. The Defendants' Instructions for Use for their mesh products failed to adequately warn Plaintiff or her physicians of numerous risks which Defendants knew or should have known were associated with the mesh, including but not limited to the risks of the products inhibition of tissue incorporation, pain, immunologic response, dehercence, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, deformation, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, intestinal obstruction, failure of repair/hernia recurrence, hernia incarceration or strangulation, or rupture/fracture of the mesh.

d. The Defendants failed to adequately warn Plaintiff or her physicians of the unusually high rate of infection associated with their mesh;

e. The Defendants failed to adequately warn Plaintiff or her physicians that the coating of Defendants' mesh is not biocompatible;

f. The Defendants failed to adequately warn Plaintiff or her physicians of the meshes propensity to shrink or contract within the body;

g. The Defendants failed to adequately warn Plaintiff or her physicians of the risk of chronic inflammation associated with the mesh;

h. The Defendants failed to adequately warn Plaintiff or her physicians of the need for corrective surgery to adjust, remove or revise the mesh;

i. The Defendants failed to adequately warn Plaintiff or her physicians of the frequency, severity, and duration of complications and risks associated with the mesh;

j. The Defendants failed to adequately warn Plaintiff or her physicians of the mesh product described hereinabove;

k. The Defendants failed to adequately warn Plaintiff or her physicians that the risks associated with their mesh deice are more frequent, severe, longer lasting, and more difficult to treat than those associated with safer feasible alternative products;

l. The Defendants failed to adequately warn Plaintiff or her physicians that their mesh is no more effective than feasible, available alternatives;

m. The Defendants failed to adequately warn Plaintiff or her physicians that use of their mesh puts patients at a greater risk of requiring additional surgery than feasible, available alternatives;

n. The Defendants failed to adequately warn Plaintiff or her physicians that use of their mesh makes any future abdominal surgery on the patient much more complex and dangerous than feasible, available alternatives;

o. The Defendants failed to adequately warn Plaintiff or her physicians of the inability to safely remove their mesh after injury, which increased the risk of future injuries;

p. The Defendants failed to adequately warn Plaintiff or her physicians that when the mesh coating is disrupted and/or degrades, ther may result in adherence or organs,

damage or organs and potentiate fistula formation; and

q. The Defendants failed to adequately warn Plaintiff or her physicians that removal of the mesh due to complications may significantly impair the patient's quality of life.

93. Defendants' failure to adequately warn Plaintiff and her surgeon of the risks associated with hernia mesh devices prevented Plaintiff and her surgeon from correctly and fully evaluating the risks and benefits of undergoing surgery with the Defendants' devices.

94. Had Defendants timely and adequately warned of the risks of the Prolene hernia mesh device used during Plaintiff's surgery, such warnings would have been heeded by Plaintiff's surgeon, in that Plaintiff's surgeon would have changed the manner in which he prescribed or selected the Prolene hernia mesh device for Plaintiff's surgery, including but not limited to, communicating the risks to Plaintiff prior to surgery, not using the Prolene hernia mesh device, and/or selecting an alternative and safer treatment option for Plaintiff.

95. If Plaintiff had been adequately warned of the life-threatening risks of the use of the Prolene hernia mesh device, as stated herein, he would have chosen an alternative treatment, one that did not carry the avoidable risks of the mesh adhering to her testicle and, therefore, would have avoided the injuries described herein.

96. Defendants' failure to adequately warn about the risk of their hernia mesh devices was a substantial and contributing factor in causing Plaintiff's injuries.

97. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

98. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages and punitive damages, together with

interest, costs of suit, attorneys' fees and all such other and further relief as ther Court deems proper.

FIFTH CAUSE OF ACTION AS AGAINST ALL DEFENDANTS (BREACH OF EXPRESS WARRANTIES)

99. Plaintiff repeats, reiterates and realleges each and every allegation of ther Complaint with the same force and effect as if more fully set forth herein.

100. Defendants expressly warranted through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their hernia mesh devices were safe, and withheld and concealed information from Plaintiff and her surgeon about the substantial risks of serious injury and/or death associated with using the products used for hernia repair surgery.

101. Defendants expressly warranted that their hernia mesh devices were safe for their intended use and as otherwise described in the complaint.

102. The Prolene hernia mesh device used on Plaintiff during her surgery did not conform to these express representations, including, but not limited to, the representation that it was well accepted in patient studies, the representation that it was safe for use, the representation that it did not have high and/or unacceptable levels of life-threatening side effects, and that it would improve or maintain health, and potentially prolong life.

103. Defendants represented that the products used for hernia repair were safer and more efficacious than other alternative surgical approaches and techniques.

104. Defendants further concealed information, regarding the true efficacy of said products.

105. Defendants' hernia mesh devices failed to conform to the foregoing express representations because their devices were not safe or effective, could produce serious side effects, degrading Plaintiff's health.

106. Defendants made these material representations, which also included omissions of material fact, to the medical and healthcare community at large, the general public, to Plaintiff's medical or healthcare provider(s), and/or to Plaintiff, with the intent to induce medical and healthcare providers and patients to dispense, provide, prescribe, accept, and/or purchase their hernia mesh devices.

107. Defendants made false material representations and/or material omissions through the course of an aggressive sales and marketing operation that implemented false and misleading statements by sales representatives, Defendant-sponsored literature, and/or Defendant-sponsored promotional functions in order to promote and sell their hernia mesh devices while omitting material facts regarding said devices' dangerous side effects and adverse events.

108. The express warranties represented by the Defendants were a part of the basis for Plaintiff and her surgeon's consent to permit the use of the Prolene hernia mesh device on Plaintiff during her 2018 hernia repair surgery.

109. Plaintiff and her surgeon relied on said express warranties in deciding to use the hernia mesh devices as a treatment option.

110. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which their hernia mesh devices were to be used, and expressly warranted the same to be in all respects safe, effective and proper for such purpose.

111. As a result of the foregoing breach of express warranty, Plaintiff was caused to suffer serious and dangerous side effects including the removal of her testicle, physical pain and

mental anguish, diminished enjoyment of life, any and all life complications caused by Plaintiff's injuries.

112. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SIXTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE)

113. Plaintiff repeats, reiterates and realleges each and every allegation of the Complaint with the same force and effect as if more fully set forth herein.

114. The Defendants impliedly represented and warranted to the users of their hernia mesh devices and patients undergoing surgery with their hernia mesh devices that said devices was safe and fit for the particular purpose for which said products were to be used, namely for the safe removal of hernias and other abdominal wall defects.

115. These aforementioned representations and warranties were false, misleading, and inaccurate in that Defendants' hernia mesh devices were unsafe, degraded Plaintiff's health and caused her significant injuries.

116. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

117. Plaintiff and her surgeon reasonably relied upon the skill and judgment of Defendants as to whether the Defendants' hernia mesh device was safe and fit for its intended use.

118. Defendants' hernia mesh devices were placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

119. Defendants breached the aforesaid implied warranty, as their hernia mesh devices, including The Prolene hernia mesh device used on Plaintiff, were not reasonably fit for their intended purposes and uses.

120. As a result of the foregoing breach of implied warranty, Plaintiff was caused to suffer serious and dangerous side effects resulting in the removal of her testicle, physical pain and mental anguish, diminished enjoyment of life, any and all life complications caused by Plaintiff's injuries.

121. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deems proper.

SEVENTH CAUSE OF ACTION AS AS AGAINST ALL DEFENDANTS (BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

122. Plaintiff repeats, reiterates and realleges each and every allegation of the Complaint with the same force and effect as if more fully set forth herein.

123. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold their Prolene hernia mesh devices for the purpose of repairing hernias and other abdominal wall defects.

124. Defendants knew and promoted the use of their Prolene hernia mesh devices for the use for which said device was to be used on Plaintiff, namely repairing hernias, improving health, maintaining health, and potentially prolonging life.

125. Defendants impliedly warranted to Plaintiff and her surgeon that their Prolene hernia mesh devices were of merchantable quality for the purposes for which they were to be used.

126. These aforementioned representations and warranties were false, misleading, and inaccurate in that the Prolene hernia mesh device used on Plaintiff was unsafe, degraded Plaintiff's health and adhered to her testicle.

127. Plaintiff and her surgeon reasonably relied on the skill, expertise and judgment of the Defendants and their representations as to the fact that the Prolene hernia mesh device selected for and used on Plaintiff was of merchantable quality.

128. Said hernia mesh devices were not of merchantable quality, in that said devices had dangerous and life-threatening side effects and; thus, were not fit for the ordinary purpose for which they were intended.

129. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering, and economic loss.

130. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as ther Court deems proper.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

161. Plaintiff realleges and incorporates by reference every allegation of their Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

162. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with her medical providers, the nature of her injuries and damages and their relationship to the defective Prolene Mesh were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statutory period for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed within the applicable statutory limitations period.

163. Ohio provides Plaintiffs with the protection of a discovery rule that allows for the tolling of the statute of limitations.

164. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff the nature of her injuries and the connection between the injuries and Defendants' tortious conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

(1) Awarding compensatory damages to Plaintiff for past and future damages including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, past health care costs, past loss of earning capacity, according to proof, together with interest and costs as provided by law;

(2) Awarding punitive damages to Plaintiff;

(3) Awarding Plaintiff's attorney's fees;

(4) Awarding Plaintiff the cost of these proceedings; and

Such other and further relief as the Court deems just and proper

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: April 5, 2022

By her attorneys:

By: /s/ Nicholas R. Farnolo

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